REMARKS

Claims 1, 3-20, and 22-32 are pending. Claims 33-37 are cancelled and claims 1 and 20 are amended. The amendments to claims 1 and 20 are supported, for example, in the specification on page 16, line 27 to page 17, line 7, and by original claims 3-6. Amendments to claims 1 and 20 are made for purposes of clarifying the claims.

Examiner Interview

Applicants thank the Examiner for the courtesy of a telephonic interview on June 18, 2007 during which applicants' attorneys, Janet S. Hendrickson and John K. Roedel and Examiners Shirley V. Gembeh and Ardin Marschel discussed proposed claim amendments and the outstanding § 112 and § 103 rejections. Examiner Gembeh indicated that the proposed claim amendments would further prosecution and that she would further consider the outstanding § 112 and § 103 rejections in view of the amendments. Examiner Marschel questioned the definitiveness of the term "comprising methionine" in claims 1 and 20 and suggested consideration of further amendments. Examiner Gembeh further stated that obvious-type double patenting rejections of the instant claims over the claims of U.S. Patent Nos. 6,187,817, 6,265,386, and 7,071,230 and a provisional rejection of claims 1, 3-20, and 22-32 over the claims of U.S. Patent Application No. 11/324,744 would be forthcoming.

The Claimed Compounds are Not *prima facie* Obvious in View of the Claims of the Cited Patents.

It is respectfully submitted that claims 1, 3-20, and 22-32 are not properly rejectable under the doctrine of obviousness-type double patenting in view of the claims of U.S. Patent No. 6,187,817, U.S. Patent No. 6,265,386, U.S. Patent No. 7,071,230 and claims 1, 3-20, and 22-32 of U.S. Patent Application No. 11/324,744.

The analysis employed in an obvious-type double patenting rejection parallels the guidelines of a 35 U.S.C. § 103 obviousness determination.[1] However, an important distinction exists. A rejection for obviousness must be based on a comparison of the claimed invention to the entirety of the disclosure in the prior art reference, whereas an obviousness-type double

[1] In re Braat, 937 F.2d 589 (Fed. Cir. 1991).

patenting rejection must be grounded on a comparison of the claimed invention to the claims, **and only the claims**, of the reference.[2]

It is respectfully submitted that the subject matter of the claims of the present application would not have been obvious in view of the claims of U.S. Patent Nos. 6,187,817, 6,265,386, and 7,071,230 or U.S. Patent Application No. 11/324,744. When evaluating the scope of a claim, every element of the claim must be considered.[3] To support an obviousness-type double patenting rejection, the claims must have been obvious at the time of filing and not merely obvious upon hindsight reconstruction using applicant's disclosure as a template to arrive at the features of the instantly claimed methods from the claims of the '817, '386, and '230 patents and the '744 application. It is respectfully submitted that the Office has failed to establish obviousness based on any reference or by evidence of the level of skill in the art or the nature of the problem that is not based upon impermissible hindsight reconstruction.

A. U.S. Patent No. 6,187,817

Subject claims 1 and 3-19 are directed to methods for reducing oral mucositis in a patient exposed to radiation, the method comprising administering to said patient an effective amount of a protective agent comprising monomeric methionine. In contrast, claims 1-28 of the '817 patent are directed to a method for preventing or reducing ototoxicity, claims 29-30 are directed to methods of preventing or reducing weight loss, claims 31-32 are directed to methods of preventing or reducing gastrointestinal toxicity, claims 33-34 are directed to methods of preventing or reducing neurotoxicity, and claims 35-36 are directed to methods of preventing or reducing alopecia wherein all of these conditions arise from treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound. Accordingly, because the claims of the '817 patent are not directed to protection of oral mucositis arising from radiation exposure, the claims do not include all the elements of subject claims 1 and 3-19.

Moreover, subject claims 20 and 22-32 are directed to methods for reducing oral mucositis in a patient treated with an anti-tumor platinum-coordination compound, the method comprising administering to said patient an effective amount of a protective agent comprising

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[2] Purdue Pharma L.P. v. Boehringer Ingelheim GMbH, 98 F.Supp.2d 362, 392, 55 USPQ2d 1168, 1190 (S.D.N.Y. 2000), *aff'd*, 237 F.3d 1359, 57 USPQ2d 1647 (Fed. Cir. 2001).
[3] See, e.g., In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

monomeric methionine. The claims of the '817 patent are described above. Although the claims of the '817 patent are directed to protection of toxicities arising from anti-tumor platinum-coordination compounds, the claims are not directed to protecting against oral mucositis. Accordingly, because the claims of the '817 patent are not directed to protection from oral mucositis, the claims do not include all the elements of subject claims 20 and 22-32.

Noting that the '817 patent may be considered a § 102(b) reference, applicant further directs the Examiner's attention to the failure of the '817 specification to have led a person of ordinary skill to the methods defined by subject claims 1 or 20. In sum, claims 1, 3-20, and 22-32 are not obvious in view of the claims of the '817 patent.

B. U.S. Patent No. 6,265,386

The subject claims are detailed above for the '817 patent. Claims 1-25 of the '386 patent are directed to a method for preventing or treating ototoxicity in a patient undergoing treatment with an aminoglycoside antibiotic comprising administering to said patient an effective amount of an otoprotective agent. Accordingly, as the claims of the '386 patent do not include the elements of "reducing oral mucositis," "patient exposed to radiation," and " treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound," the claims of the '386 patent do not include all the elements of the subject claims. Further, a person of ordinary skill would not have found the instant claims for "reducing oral mucositis" obvious from the '386 claims because the claims of the '386 patent are directed to "treating or preventing ototoxicity." Thus, only impermissible hindsight would have allowed such a person of ordinary skill to have found claims 1, 3-20 and 22-32 obvious.

Further, noting that the '386 patent may be considered a § 102(b) reference, applicant further directs the Examiner's attention to the failure of the '386 specification to have led a person of ordinary skill to the methods defined by subject claims 1 or 20.

C. U.S. Patent No. 7,071,230

The claims of the '230 patent are directed to methods for preventing or treating ototoxicity in a patient exposed to noise. Because the claims of the '230 patent do not include the elements of "reducing oral mucositis," "patient exposed to radiation," and "treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound," the

claims of the '230 patent do not include all the elements of the subject claims. Further, a person of ordinary skill would not have found the instant claims for "reducing oral mucositis" obvious from the '230 claims because the claims of the '230 patent are directed to "treating or preventing ototoxicity." Also, the '230 claims are directed to methods for treating patients exposed to noise and the instant claims are directed to treating patients exposed to radiation or undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound. Thus, only impermissible hindsight would have allowed a person of ordinary skill to have found the instant claims 1, 3-20 and 22-32 obvious from the claims of the '230 patent.

In addition, noting that the '230 patent may be considered a § 102(b) reference, applicant further directs the Examiner's attention to the failure of the '230 specification to have led a person of ordinary skill to the methods defined by subject claims 1 or 20.

D. U.S. Application Serial No. 11/324,744

The claims of the '744 application are directed to methods for preventing or treating ototoxicity in a patient exposed to noise. Because the claims of the '744 application do not include the elements of "reducing oral mucositis," "patient exposed to radiation," and "treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound," the claims of the '744 application do not include all the elements of the subject claims. Further, a person of ordinary skill would not have found the instant claims for "reducing oral mucositis" obvious from the '744 claims because the claims of the '744 application are directed to "treating or preventing ototoxicity." Also, the '744 claims are directed to methods for treating patients exposed to noise and the instant claims are directed to treating patients exposed to radiation or undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound. Thus, only impermissible hindsight would have allowed a person of ordinary skill to have found the instant claims 1, 3-20 and 22-32 obvious from the claims of the '744 application.

In summary, a person of ordinary skill would not have found the instant methods for reducing oral mucositis arising from exposure to radiation or administration of anti-tumor platinum-coordination compounds obvious upon consideration of the claims of the cited patents and applications. It is, therefore, respectfully submitted that claims 1, 3-20 and 22-32 are not obvious in view of the claims of the '817, '386, and '230 patents and the '744 application.

CONCLUSION

Applicant submits that the present application is now in a condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,

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